Citation:

Phung OJ, Makanji SS, White CM, Coleman CI. Almonds have a neutral effect on serum lipid profiles: a meta-analysis of randomized trials. *J Am Diet Assoc*. 2009 May;109(5):865-73.

PubMed ID: <u>19394473</u>

Study Design:

Meta-analysis

Class:

M - <u>Click here</u> for explanation of classification scheme.

Research Design and Implementation Rating:



POSITIVE: See Research Design and Implementation Criteria Checklist below.

Research Purpose:

To evaluate the influence of almonds on lipid parameters.

Inclusion Criteria:

Articles included in this study were found through a systematic literature search of MEDLINE, EMBASE, Cochrane CENTRAL and the Natural Medicines Comprehensive Database from earliest date through July 2008 using the keywords: almonds, Prunus dulcis, Prunus, oleum amygdalae, amygdalus and Prunus amygdalus dulcis; or through manual search of references.

Randomized controlled trials of almonds in human participants that reported efficacy data on at least one lipid parameter: total cholesterol, LDL cholesterol, HDL cholesterol, triglycerides or the LDL:HDL ratio were included.

Exclusion Criteria:

Articles were excluded due to duplicate citation, not evaluating almonds, non-systemic exposure to almonds, not randomized controlled trials, not human studies, patients < 18 years of age, almonds evaluated with other functional foods, not controlled trials, repeat report of another study, no lipid data, extensively confounded (weight loss) and/or data not in useable form.

Description of Study Protocol:

Recruitment

Articles included in this study were found through a systematic literature search of MEDLINE, EMBASE, Cochrane CENTRAL and the Natural Medicines Comprehensive Database from earliest date through July 2008 using the keywords: almonds, Prunus dulcis, Prunus, oleum amygdalae, amygdalus and Prunus amygdalus dulcis; or through manual search of references.

Design: Meta-analysis of 5 randomized controlled studies

Blinding used (if applicable):

Blinding was not used in the meta-analysis but was reported for each of the individual studies: 3 open-label, 1 single-blind, 1 double-blind.

Intervention (if applicable): not applicable

Statistical Analysis: StatsDirect, version 2.4.6, 2005, StatsDirect Ltd, Cheshire, UK

Mean, weighted mean difference, DerSimonian and Laird random-effects models, Confidence intervals, I^2 statistic for heterogeneity, funnel plots, Egger's weighted regression for publication bias and the Grading of Recommendations Assessment, Development Working Group system for assessing strength of evidence were used in the presentation of the analysis.

Data Collection Summary:

Timing of Measurements

Each study followed subjects for 4 weeks both on and off of respective interventions.

Dependent Variables

- Total cholesterol
- Low density lipoprotein (LDL) cholesterol
- High density lipoprotein (HDL) cholesterol
- Triglycerides
- HDL:LDL ratio

Independent Variables

• Almond consumption

Control Variables

- Age
- Sex
- Comorbidities

Description of Actual Data Sample:

Initial N: 88 non-duplicate citations led to 16 full-text article evaluations.

Attrition (final N): 5 randomized controlled trials included in analysis, representing n=142 participants, 63% male.

Age: 18-86 years

Ethnicity: not specified

Other relevant demographics: 40% with known hyperlipidemia, 21% with type 2 diabetes

Anthropometrics: not specified

Location: not specified for individual studies, authors based in Connecticut, USA

Summary of Results:

Key Findings

- Almonds significantly lowered total cholesterol (p=0.03).
- No statistically significant effect of almonds on LDL cholesterol (p=0.05) overall but there was significant reduction of LDL in patients with hyperlipidemia and without diabetes (p=0.03).
- HDL cholesterol was lowered significantly in patients with hyperlipidemia (p=0.04) but almonds did not significantly impact HDL in other patients or overall (p=0.08).
- No statistically significant effect of almonds on triglycerides (p=0.58) or the LDL:HDL ratio (p=0.67).

Other Findings

- The Almond Board of California funded or co-funded 4 of the 5 studies and funding of remaining study was unknown.
- No statistical heterogeneity observed in any lipid parameter ($l^2=0\%$ all).
- There was a low likelihood of publication bias in all analyses (p>0.25 for all)
- Moderate strength for total and LDL cholesterol
- Low strength for HDL cholesterol, triglycerides and LDL:HDL ratio

Author Conclusion:

Almond consumption can reduce total cholesterol concentrations, but does not appear to significantly affect LDL and HDL cholesterol, triglycerides, or the LDL:HDL ratio.

Reviewer Comments:

Authors note the following limitations:

- Potential for participants to inaccurately recall their past nut consumption
- It is possible that this meta-analysis, despite pooling 5 trials, was still underpowered to demonstrate statistical significance for some endpoints or subgroups
- Different background diets may result in differing degrees of weight change during trials, potentially confounding the results of the meta-analysis, because weight loss by itself is a known cause of lipid modulation
- Attrition bias may be a concern, however, reporting of compliance to study diets was rarely reported

Research Design and Implementation Criteria Checklist: Review Articles

Relevance Questions

1. Will the answer if true, have a direct bearing on the health of patients?



2.	Is the outcome or topic something that patients/clients/population groups would care about?	Yes
3.	Is the problem addressed in the review one that is relevant to nutrition or dietetics practice?	Yes
4.	Will the information, if true, require a change in practice?	Yes

Validity Questions			
1.	Was the question for the review clearly focused and appropriate?	Yes	
2.	Was the search strategy used to locate relevant studies comprehensive? Were the databases searched and the search termsused described?	Yes	
3.	Were explicit methods used to select studies to include in the review? Were inclusion/exclusion criteria specified and appropriate? Were selection methods unbiased?	Yes	
4.	Was there an appraisal of the quality and validity of studies included in the review? Were appraisal methods specified, appropriate, and reproducible?	Yes	
5.	Were specific treatments/interventions/exposures described? Were treatments similar enough to be combined?	???	
6.	Was the outcome of interest clearly indicated? Were other potential harms and benefits considered?	Yes	
7.	Were processes for data abstraction, synthesis, and analysis described? Were they applied consistently across studies and groups? Was there appropriate use of qualitative and/or quantitative synthesis? Was variation in findings among studies analyzed? Were heterogeneity issued considered? If data from studies were aggregated for meta-analysis, was the procedure described?	Yes	
8.	Are the results clearly presented in narrative and/or quantitative terms? If summary statistics are used, are levels of significance and/or confidence intervals included?	Yes	
9.	Are conclusions supported by results with biases and limitations taken into consideration? Are limitations of the review identified and discussed?	Yes	
10.	Was bias due to the review's funding or sponsorship unlikely?	???	

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